7. STANDARDS FOR THE PURITY AND QUALITY OF BOTANICAL MEDICINES OR SUBSTANCES

Botanical medicines or substances are to be as free as practicable from insects or other animal life, animal material or animal excreta. They are to be free from mold and shall show no discoloration, abnormal odor, or deterioration due to any cause.

General Treatment of Fresh Succulent and Dried Substances

Freshly gathered whole plants, flowers, and such roots as are to be used in their fresh state should be kept in a cool place and be made into tinctures as soon as possible. If this cannot be done at once, such substances should not be allowed to dry. This is best prevented by keeping them in a refrigerator or other place, the temperature of which is as cool as possible, avoiding freezing. They should not be immersed in water, but merely sprinkled, in order not to extract or dilute the natural juice, the proportion of which is to be ascertained and considered as a part of the menstruum in making a standard tincture.

The treatment of dried substances is different. Odorous substances are to be kept perfectly isolated, in tightly closed boxes or vessels adapted to this purpose, in order that the peculiar odor of such drugs may not be imparted to others. The precautions made use of should include those against light, heat and moisture.

8. LIQUID PREPARATIONS OF DRUGS

All substances soluble in the previously described menstrua or vehicles are to be made into solutions or tinctures and their attenuations, but such moist and/or soluble substances may also be made into triturations with lactose. Below 8X, all insoluble substances or partially soluble substances should be made into triturations only.

The first solution or tincture is made in the proportion of 1/10 in water or alcohol of suitable strength, unless otherwise specified in the monograph.

Aqueous solutions are made of substances which are soluble in water but not in alcohol, or of those which, when soluble in alcohol, are subject to chemical change or decomposition. Aqueous solutions are, as a rule, unstable, and will keep but a short time.

Solutions of chemical substances are to be made on the decimal scale, that is, in the proportion of one (1) part by weight of soluble medicinal substance (solid or liquid) to which is added sufficient solvent to make ten (10) parts by volume of solution, and hence equal to the first decimal dilution, to be marked 1X.

If not soluble in the proportion of 1 to 10, they should be made by adding one (1) part by weight of medicinal substance to 99 parts by volume of sufficient solvent to make one hundred (100) and the solution marked 2X (or 1C).

If liquid substances contain water, this also should be deducted from that contained in the solvent, and the anhydrous substance taken as the unit of strength.

9. TINCTURES OR ALCOHOLIC SOLUTIONS

Most medicines used in homoeopathic practice can be prepared in the form of tinctures (as well as in the form of attenuations). Tinctures, also referred to as "mother tinctures", are made from a variety of zoological or botanical substances which are wholly or partially soluble in alcohol of various strengths. Such substances comprise all plants and parts of plants, such as bark, root, wood, fruit, bud, flower, seed, resin, gum, and balsam.

b. TINCTURES OF ZOOLOGICAL SUBSTANCES

Zoological substances comprise living or dried insects or other animals, or parts of animals.

Tinctures of zoological substances are obtained by maceration in alcohol at 65 percent v/v, except in some cases specified in the monographs. These tinctures are made to represent one (1) part by weight of the crude material in 20 parts by weight of completed solution.

The preparation of these tinctures is made according to the following process of maceration:

- put the crude substance, suitably divided, into the quantities of alcohol and water calculated to obtain a 1/20 tincture with an alcohol strength of 65% v/v. Allow maceration for not less than three weeks, stirring sufficiently. Decant, allow to stand for 48 hours, and filter.

The tinctures resulting from either the process of maceration or percolation from botanical or zoological substances are filtered directly into containers of glass or other inert materials. These shall be stoppered and placed in an appropriate area, each to be marked with the sign ø, indicating the strongest liquid preparation made directly from the medicinal substance, and also showing the proportion of medicinal substance which the tincture represents. Except in special cases specified in the monographs, the shelf life of the tinctures is five years from the manufacturing date. The shelf life or its attendant expiration date shall apply only to the tincture as a finished dosage form, and not to any subsequent dilution or product prepared from it.

Before use, tinctures of botanical and zoological origin are subjected to tests and assays according to classical analytical procedures:
- description: color, odor, and taste;
- identification: identity reactions are made to reveal the presence of a specific constituent or a group of constituents such as alkaloids, etc.;
- test: determination of the alcohol content and non-volatile residue, and thin-layer chromatographic analysis;
- assay when the tincture contains an active principle in measurable amounts.

10. ATTENUATIONS

The Pharmacopoeia Convention hereby adopts the decimal, centesimal and fifty millesimal systems as the standard scales of attenuation and notation, under which each successive attenuation or trituration contains just 1/10, 1/100 or 1/50,000 as much of the drug substance as the preceding attenuation or trituration.

a. DECIMAL SCALE OF ATTENUATION

One milliliter (1.0 ml) of tincture, one milliliter of 1X aqueous solution, or one gram (1.0 g) of 1X trituration represents 0.10 gram of dry crude medicinal substance.

One milliliter (1.0 ml) of 2X attenuation, or one gram (1.0 g) of 2nd trituration contains 0.01 gram of the dry crude medicinal substance.

Subsequent liquid or solid attenuations are made by serial progression, succussing or triturating one (1) part of the preceding attenuation to nine (9) parts of the vehicle, and represent the following proportions of active principle (i.e., dried medicinal substance):

$2X = 10^{-2}$	$6X = 10^{-6}$
$3X = 10^{-3}$	$7X = 10^{-7}$
$4X = 10^{-4}$	$8X = 10^{-8}$
$5X = 10^{-5}$	

b. CENTESIMAL SCALE OF ATTENUATION

One milliliter (1.0 ml) of the first centesimal liquid attenuation (1C), or one gram (1.0 g) of the first centesimal trituration (1C) represents 0.01 gram (10.0 mg) of the dry crude medicinal substance.

One milliliter (1.0 ml) of the 2nd centesimal liquid attenuation (2C), or one gram (1.0 g) of the 2nd centesimal trituration (2C) represents 0.0001 gram (0.1 mg) of the dry crude medicinal substance.

Subsequent liquid or solid attenuations are made by serial progression, succussing or triturating one (1) part of the preceding attenuation to 99 parts of the vehicle, and represent the following proportions of active principle (i.e., dried medicinal substance):

$2C=10^{-4}$ $4C=10^{-8}$
$3C=10^{-6}$

c. FIFTY MILLESIMAL SCALE OF ATTENUATION

One milliliter (1.0 ml) of the first fifty millesimal attenuation (1LM) represents 4.0×10^{-9} g of dry crude medicinal substance.

One milliliter (1.0 ml) of the second fifty millesimal attenuation (2LM) represents 8.0×10^{-11} g of dry crude medicinal substance.

Method of Manufacture (see Figure 1)

1. For solid substances, proceed according to the centesimal scale to the 3C trituration (see section 12, "Solid Attenuations: Triturations"). Initially, for liquid substances, impregnate the lactose in a proportion of 1 to 100 beginning with the liquid substance (mother tincture), then triturate. The second and third triturations are carried out in the same way as when starting with solid products.
2. Take 0.062 g. of the 3C trituration, add 500 drops of a mixture composed of 1 part 95% v/v alcohol and 4 parts distilled water.
3. Add 1 drop from the result of step 2 to 2.0 ml. of 95% v/v alcohol. Succus. The result is the 1LM.
4. Pour 1 drop of the 1LM on 0.575 g. #10 pellets (500 #10 pellets). Take 1 pellet and add to 2.0 ml. of 95% v/v alcohol. Succus. The result is the 2LM.
5. Pour 1 drop of the 2LM on 0.575 g. #10 pellets (500 #10 pellets). Take 1 pellet and add to 2.0 ml. of 95% v/v alcohol. Succus. The result is the 3LM.
6. Repeat step 5 until the 30LM is obtained.

11. LIQUID ATTENUATIONS

In the decimal scale the original quantity of medicine is divided progressively by ten so that the first decimal (1X) contains 1/10, the second decimal (2X) 1/100, and the third decimal (3X) 1/1000 of the original substance suspended in, and attenuated or expanded by, the diluent (alcohol, water, etc.). Each tincture (with some exceptions to be stated) is equal or equivalent in medicinal strength to the first decimal attenuation (1/10), designated 1X.

Where certain substances are insoluble in the proportion of 1 to 10 and require more solvent, e.g., *Arsenicum album, Phosphorus, Sulfur,* etc., their original solutions shall be prepared in accordance with the respective monographs. In the centesimal scale the 1X solution or tincture is divided by 10 to produce the first centesimal (1C), then by 100 to produce each succeeding attenuation, 2C, 3C, 4C, etc.

moeopathic liquid attenuations are designated according to the method of attenuation. The designations, wh__n must appear on the labels, are shown in the following table:

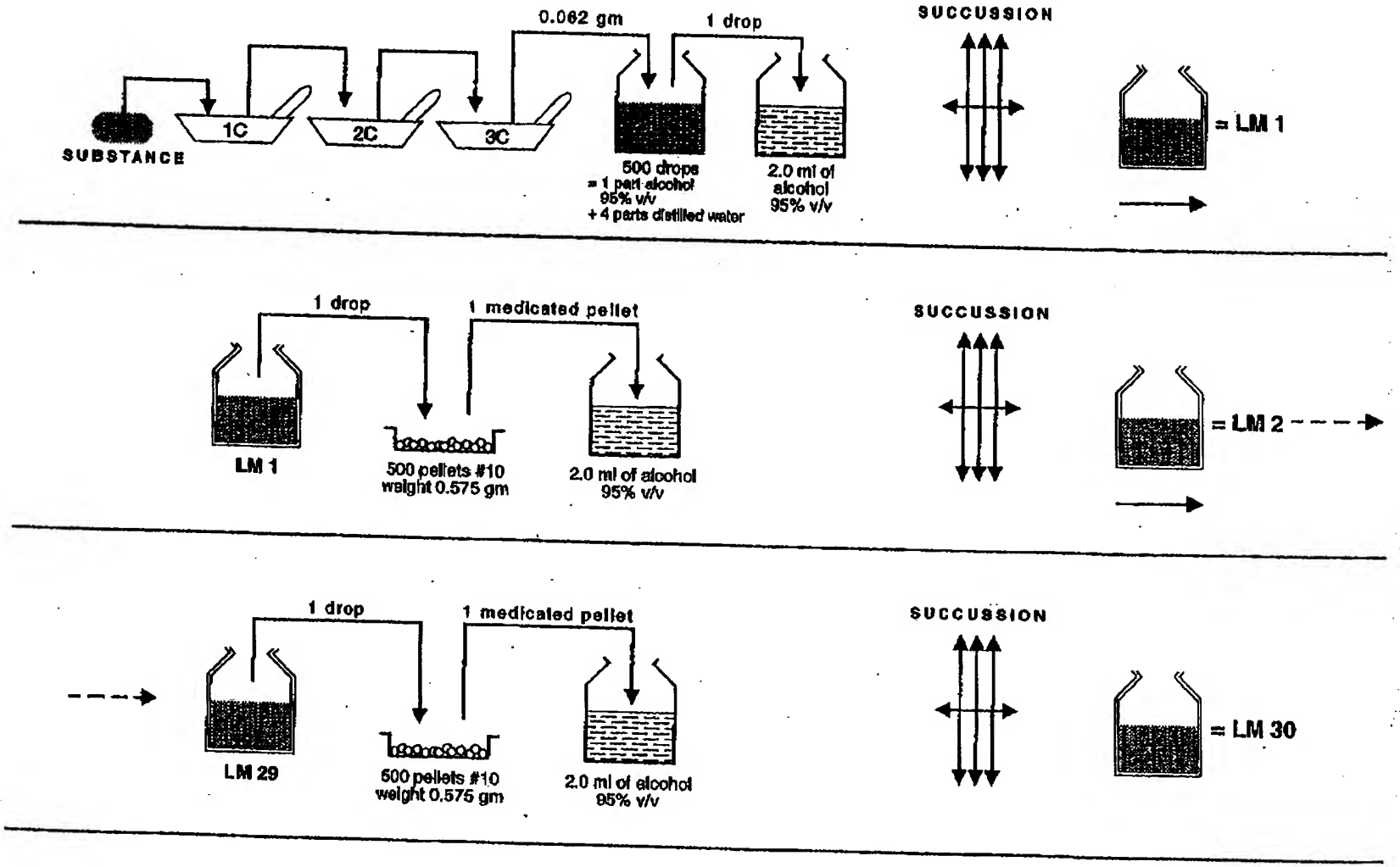

Figure 1. Method for Preparing Fifty Millesimal (LM) Potencies

Designation	Scale	Method of Attenuation
X or D	Decimal (1/10)	Hahnemannian
CH or C	Centesimal (1/100)	Hahnemannian
CK or K	Centesimal (1/100)	Korsakovian
LM	Fifty Millesimal (1/50,000)	Hahnemannian

The preferred designation for decimal attenuations is X, which clearly indicates the scale used. All decimal attenuations are prepared according to the Hahnemannian method.

The preferred designation for Hahnemannian centesimal attenuations is CH, which clearly indicates both the scale used and the method of attenuation. As C is a synonym of CH, it can be only used to designate an attenuation that is prepared according to the Hahnemannian method.

The preferred designation for Korsakovian centesimal attenuations is CK, which clearly indicates both the scale used and the method of attenuation.

The designation M refers to neither scale nor method of attenuation. M is equivalent to 1000, and is used in place of the numeral 1000 in Korsakovian centesimal attenuations. For example, 1M indicates a 1000 CK attenuation, 10M a 10,000 CK attenuation.

a. HAHNEMANNIAN ATTENUATIONS - MULTIPLE FLASK METHOD OF PREPARATION

A new, well-cleaned, stoppered glass vial of appropriate capacity is employed.

One part (e.g. 1.0 ml of tincture or 1X solution) is poured into this vial. Nine parts (e.g. 9.0 ml) of diluent is ¹ed (if the tincture represents 1/20 of the crude medicinal substance, pour 2.0 ml of this tincture and add 8.0 of diluent). This mixture is succussed thoroughly and labeled 2X.

In a new, well-cleaned, stoppered glass vial, pour 1.0 ml of 2X attenuation and 9.0 ml of diluent; with appropriate succussion the 3X attenuation is obtained.

Continue this procedure until the desired attenuation level is attained.

In order to prevent possible misinterpretation of the detailed instructions for the preparation of attenuations of soluble substances, it is emphasized that the above instructions are for the decimal system.

Attenuations may be prepared according to the centesimal system in a similar manner, with appropriate adjustment of the proportions of medicinal substance and diluent.

b. KORSAKOVIAN ATTENUATIONS - SINGLE FLASK METHOD OF PREPARATION

A well-cleaned stoppered glass vial of appropriate capacity is employed.

Add a measured volume of the tincture to the vial. Succuss thoroughly and empty the vial either by turning it upside down or by suction. The emptying process employed must remove 99 percent of the original volume of tincture, leaving 1 percent of the original volume in the vial.

Add 99 parts of diluent to the 1 part tincture remaining in the vial. Succus thoroughly. The resulting solution is the first Korsakovian attenuation, designated 1CK.

Empty the vial once more. Add 99 parts of diluent to the 1 part of the 1CK remedy. Succus thoroughly. The re· ¹ting solution is the second Korsakovian attenuation, designated 2CK.

Continue this procedure until the desired attenuation level is attained.

With respect to substances that are not soluble in water or alcohol, prepare three successive triturations (to 1/100) in lactose. Then move on to the liquid phase and follow the procedure outlined above.

Either the Hahnemannian or Korsakovian method can be used until the 200th attenuation; thereafter, the Korsakovian system generally is used.

For liquid attenuations intended for medicating purposes, Dispensing Alcohol should be used for the final liquid attenuation.

When homœopathic solutions are intended for oral or sublingual administration in liquid form, the final attenuation may be prepared with an appropriate percentage of alcohol:
- alcohol at 60 percent v/v: for the 2X attenuation obtained from a tincture when appropriate;
- alcohol at a minimum of 20 percent v/v: for the other attenuations.

This paragraph may supersede the requirements within the section "Classification of Drugs" with reference to the use of dispensing alcohol.

A Homeopathic solution intended for oral or sublingual administration in liquid form may be produced in non-alcoholic media, provided the final dosage form is prepared with a suitable preservative system and is protected from decomposition. Any preservative agent must comply with USP standards.

12. SOLID ATTENUATIONS: TRITURATIONS

1. Attenuations of solid substances are prepared by trituration of the crude substance with Lactose, U.S.P., in a mortar and pestle for small amounts or in a mechanical triturator for large amounts, in the proportion of one (1) part by weight of the crude substance and nine (9) parts by weight of lactose to produce the 1X trituration.

2. As with liquid attenuations, in the decimal scale each step is accomplished by triturating one (1) part of the original attenuation with nine (9) parts of lactose. In the centesimal scale, one (1) part by weight of the 1X trituration is triturated with nine (9) parts by weight of lactose to produce the 1C trituration, then is divided by 100 to produce each succeeding trituration, 2C, 3C, 4C, etc.

Triturations may be dispensed in the form of powders or tablet triturates, either of which may be dissolved in or mixed with aqueous solutions.

13. ATTENUATIONS FROM MICROSCOPIC FUNGAL STRAINS

Given the risk of contamination during handling of fungal strains, these attenuations are prepared under a laminar flow hood.

Equipment for each strain (to be sterilized the day before in a drying oven, for 1 hour at 150° C.):
- 15 mL bottle.....1
- 250 mL bottle.....2
- 500 mL bottle.....2
- 1 liter bottle.....1
- No. 3 sintered glass funnel.....1

Additional equipment:
- Big jar, filled with bleach, in which the 15 mL bottle, 500 mL bottles, and sintered glass funnel can be placed.....1
- 60 mL bottle of 30% v/v alcohol.....1
- 1 liter bottle of 70% v/v alcohol.....1
- Platinum handle.....1

Preparation of the 1C attenuation:

Place 5 mL of 30% v/v alcohol in a 15 mL bottle. Place the carded cotton near the burner. Take the culture tube and, using pliers, remove the stopper close to the flame of a Bunsen burner.

First, flame the platinum handle *along its entire length* and allow it to cool. Then use it to scrape as much culture as possible and to put it into the 15 mL bottle, while trying to crush the strain against the sides of the bottle in order to obtain a homogeneous suspension (this, of course, depends on the consistency of the strain). Stopper the 15 mL bottle.

Flame the platinum handle again. It should be passed through the flame in a horizontal position, from left to right. *This should be done slowly to avoid splattering the strain.*

Use metal tongs and flame the carded cotton. Stopper the culture tube after having passed the mouth of the tube through the flame.

Potentize the 15 mL bottle. A 1C attenuation is obtained.

Preparation of the 2C attenuation:

Place 400 mL of 70% v/v alcohol in a 500 mL bottle, then add the 5 mL of the 1C fungal strain suspension. Place the 15 mL bottle in the jar of bleach. It is not necessary to rinse the 15 mL bottle containing the suspension.

Wipe the stopper and rim of the 500 mL bottle with an alcohol-soaked piece of cotton to remove any possible fungal suspension. *Be very cautious when opening the bottle to prevent contaminating the work area with suspension on the rim of the bottle and in the stopper.*

Add 95 mL of 70% v/v alcohol to the 500 mL bottle. Stopper the bottle. Potentize the 500 mL bottle. A 2C attenuation is obtained. Wipe everything carefully with an alcohol-soaked piece of cotton.

This 2C attenuation is filtered in the sintered glass funnel and is collected in a single one-liter bottle to achieve homogeneity. (When the filtrate is collected in a single bottle, a slight shake of the bottle is enough to set the fungal strain into suspension again. In this manner, the risk of contamination via suspension on the lip of the bottle is decreased).

The 500 mL bottle and the sintered glass funnel that was used for filtering is placed in the jar of bleach for 48 hours. It is then rinsed with water and sterilized.

Separate the filtrate obtained into two 250 mL stoppered bottles (in case of breakage). Cover the stoppers with paraffin.

Preparation of the 3C attenuation:

The 2C attenuation is allowed to sit for 3 days to permit the sterilizing effect of the alcohol to operate on the fungal strain.

Place 400 mL of 70% v/v alcohol and 5 mL of the 2C attenuation in a 500 mL bottle. It is *imperative* that this 2C attenuation be taken up by means of a sterile pipette, the end of which has been stoppered with a piece of cotton to prevent the liquid from being accidentally swallowed.

Add 95 mL of 70% v/v alcohol. Stopper the bottle. Potentize. A sterile 3C attenuation is obtained. Wipe everything with an alcohol-soaked piece of cotton.